

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CARL D. CACHIA, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

BELLUS HEALTH INC., ROBERTO
BELLINI, FRANÇOIS DESJARDINS, DR.
CATHERINE BONUCCELLI, DR. JACKY
SMITH, JEFFERIES LLC, COWEN AND
COMPANY, LLC, GUGGENHEIM
SECURITIES, LLC, ROBERT W. BAIRD &
CO. INCORPORATED, and BLOOM
BURTON SECURITIES INC.,

Defendants.

No. 1:21-CV-02278-GBD

Date of Service: January 7, 2022

ORAL ARGUMENT REQUESTED

**DEFENDANT DR. JACKY SMITH'S MEMORANDUM OF LAW IN SUPPORT OF
HER MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT**

Defendant Dr. Jacky Smith respectfully submits this memorandum of law in support of her motion, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss the Amended Complaint filed by plaintiff Carl D. Cachia (“Plaintiff”). Dr. Smith joins the motion to dismiss filed by Defendants BELLUS Health Inc. (“BELLUS,” or “the Company”), Roberto Bellini, Dr. Catherine Bonuccelli, and Francois Desjardins (collectively with BELLUS, “Co-Defendants”) (Dkt. Nos. 54-56) to the extent applicable.

PRELIMINARY STATEMENT

Plaintiff’s sole claim against Dr. Smith should be dismissed for the reasons set forth in Co-Defendants’ memorandum of law in support of their motion to dismiss the Amended Complaint (“Co-Defendants’ Mot. to Dismiss”) at Parts I, III, and V. Co-Defendants’ arguments apply especially to Dr. Smith, a Professor at the University of Manchester in the United Kingdom who is not an employee of BELLUS. In his amended pleading, Plaintiff improperly dragged Dr. Smith into this litigation without particularized allegations of wrongdoing by her. Indeed, Plaintiff’s 98-page Amended Complaint musters only a handful of allegations that pertain at all to Dr. Smith. These bare allegations cannot withstand a motion to dismiss.

STATEMENT OF FACTS & PROCEDURAL HISTORY

Dr. Smith incorporates by reference the statement of facts set forth in the Background section of Co-Defendant’s Memorandum of Law.¹ As it pertains to Dr. Smith specifically, the Amended Complaint describes her as “a Professor of Respiratory Medicine at the University of Manchester, United Kingdom” who “ran a multi-disciplinary research team whose focus was on understanding mechanisms underlying pathological cough[.]” (Amended Complaint (“AC”))

¹ For the purposes of this motion to dismiss only, Dr. Smith accepts as true the non-conclusory factual allegations in the Amended Complaint. *See Rombach v. Chang*, 355 F.3d 164, 169 (2d Cir. 2004). Conclusory allegations in a complaint “are not entitled to the assumption of truth” on a motion to dismiss. *Francis v. Kings Park Manor, Inc.*, 992 F.3d 67, 72 (2d Cir. 2021).

¶ 32.) It describes “[h]er main research interests [as] focused on developing new endpoints in cough monitoring, understanding the mechanisms underlying cough in respiratory diseases and the testing of novel anti-tussive therapies.” (*Id.*) Plaintiff further describes Dr. Smith’s role as an “advisor” for BELLUS who served “as the Principal Investigator of BELLUS’s Phase 2 RELIEF trial of BLU-5937 and/or the Chairman of the Clinical Advisory Board.” (*Id.*)

As described in the Amended Complaint, Dr. Smith spoke at two Key Opinion Leader (“KOL”) meetings hosted by BELLUS, and Plaintiff seemingly takes issue with Dr. Smith’s statements at the second of the two meetings, which took place on May 27, 2020. (*Id.* ¶¶ 33, 166-168, 172-73.) Plaintiff alleges in a handful of paragraphs that at this second KOL meeting, during which Dr. Smith and others discussed the state of chronic cough treatment (*id.* ¶ 33), Dr. Smith described the design and objective of the RELIEF study (*id.* ¶¶ 166-168), and its relation to studies conducted by other drug companies. (*Id.* ¶¶ 172–73.) For example, Plaintiff highlights Dr. Smith’s statement that BELLUS “*select[ed] patients with more than 10 coughs per hour*” for the RELIEF study. (*Id.* ¶ 167 (emphasis in original).) While Plaintiff does not seemingly identify any particular statement made by Dr. Smith to be factually untrue, Plaintiff alleges that Dr. Smith’s statements at this KOL meeting were misleading because she failed to disclose “the design flaw in BELLUS’s Phase 2 trial,” as a result of which “there was a high risk [that drug candidate BLU-5937] would not meet its designated primary endpoint for efficacy[.]” (*See id.* ¶¶ 166–69, 172–74.)

Notably, this May 27, 2020 KOL meeting occurred more than six months after BELLUS’s September 2019 IPO closed and more than one month after BELLUS’s alleged “partial disclosure” that a Phase 2b trial might be necessary if no minimum efficacy dose was observed. (*Id.* ¶¶ 7, 33, 196.) Thus, the only alleged misstatements attributed to Dr. Smith in the

Amended Complaint took place *after* the first alleged stock drop. (See AC ¶¶ 166–68, 172–73, 196–97.)

Plaintiff filed this action on March 16, 2021, and Dr. Smith was not named as a defendant at that time. When Plaintiff filed the Amended Complaint more than six months later, on September 17, 2021, he added Dr. Smith as a defendant, naming her in Count One of the five-count Amended Complaint, which asserts a fraud-based claim pursuant to § 10(b) of the Securities Exchange Act of 1934 (the “Exchange Act”).

ARGUMENT

I. Plaintiff fails to state a claim under the Exchange Act.

Plaintiff’s sole claim against Dr. Smith is based on a myriad of conclusory allegations that are insufficient to meet ordinary pleading standards, much less the heightened pleading standards of the Private Securities Litigation Reform Act (“PSLRA”). *See ECA, Local 134 IBEW Joint Pension v. JP Morgan Chase*, 553 F.3d 187, 194 (2d Cir. 2009). The absence of particularized allegations concerning Dr. Smith is fatal to Plaintiff’s claim against her.

A. Plaintiff fails to plead facts giving rise to a strong inference of scienter.

Dr. Smith joins in the arguments made by Co-Defendants in Section I.A of their motion to dismiss the Amended Complaint. As Co-Defendants explained, Plaintiff “make[s] no attempt to establish scienter with respect to each Individual Defendant” which, by itself, “warrants dismissal.” *Schaffer v. Horizon Pharma plc*, No. 16-cv-1763 (JMF), 2018 WL 481883, at *11 (S.D.N.Y. Jan. 18, 2018). Plaintiff has alleged no facts giving rise to an inference of the requisite state of mind in Dr. Smith, let alone particularized facts giving rise to the “strong inference” required under the PSLRA. *See ECA, Local 134 IBEW Joint Pension*, 553 F.3d at 198. Plaintiff has not alleged that Dr. Smith – who was not an employee of BELLUS – stood to reap *any* benefit from her role in designing and conducting a clinical trial that she allegedly knew

faced “a high risk” of failing to meet the Company’s “designated primary endpoint for efficacy” and from allegedly concealing that fact from investors. (AC ¶ 169.) Nor has Plaintiff alleged any facts supporting an inference – much less the “correspondingly greater” burden of establishing the requisite “strong inference” where allegations of motive are absent, *ECA*, 553 F.3d at 199 – that Dr. Smith knew or recklessly disregarded information suggesting that the RELIEF study was at “high risk” of not meeting its designated endpoint.

Having made no allegations raising an inference of scienter, Plaintiff has utterly failed to raise an inference that is “cogent and at least as compelling” as the obvious non-fraudulent inference – namely, that Dr. Smith designed a clinical trial and corresponding enrollment criteria that she believed in. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). Indeed, unlike earlier comparable studies that had no minimum cough frequency requirement, the RELIEF study actually required patients to have a minimum cough frequency of 10 coughs per hour. (AC ¶ 124.) It is nonsensical and defies logic to suggest that Dr. Smith assisted in designing and conducting a study that she believed was doomed to fail.²

Accordingly, the Amended Complaint does not satisfy the requisite “strong inference” of scienter.

B. Plaintiff fails to plead any actionable statements against Dr. Smith.

In addition to Plaintiff’s failure to allege facts that give rise to a strong inference of scienter on the part of Dr. Smith, Plaintiff has not pleaded any actionable statements for which

² Subsequent to the RELIEF trial, BELLUS designed and conducted a Phase 2b trial for BLU-5937, and BELLUS recently announced positive results from that trial. *See* Press Release, BELLUS Health, BELLUS Health Announces Positive Topline Results from its Phase 2b SOOTHE Trial of BLU-5937 for the Treatment of Refractory Chronic Cough (Dec. 13, 2021), *available at* <http://ir.bellushealth.com/news-releases/news-release-details/bellus-health-announces-positive-topline-results-its-phase-2b>.

Dr. Smith is liable. First, the statements directly attributable to Dr. Smith are not, in fact, actionable. Second, despite Plaintiff's efforts to hold Dr. Smith liable for allegedly actionable statements made by others (*see* AC ¶ 37), Dr. Smith was not the "maker" of these statements and cannot be held liable for them under the group pleading doctrine.

1. None of the statements attributed to Dr. Smith in the Amended Complaint are actionable.

While Plaintiff does not single out any of Dr. Smith's statements as affirmatively untrue, Plaintiff alleges that certain statements she made were misleading because she allegedly "failed to disclose that BELLUS had disregarded, in designing its P2X3 Phase 2 trial, the correlation between high cough frequency and high efficacy that Merck's studies had demonstrated" and that this "design flaw . . . meant there was a high risk [that BLU-5937] would not meet its designated primary endpoint for efficacy[.]" (AC ¶ 169.) As described at length in Co-Defendant's motion to dismiss, the statements attributed to Dr. Smith are not actionable for one or more of the following reasons: (1) Plaintiff fails to allege material information available at the time of Dr. Smith's statements that was omitted and that rendered her statements materially misleading; (2) the actual statements Dr. Smith made were true, and not false or misleading; (3) the very fact that Plaintiff now alleges to be a "design flaw" of the RELIEF trial (i.e. that the enrollment criteria included a cough frequency threshold of 10 coughs per hour) *was* disclosed (*see, e.g.*, AC ¶ 167) and information regarding other clinical trial designs was publicly available, and there was no duty to disclose anything further; (4) Dr. Smith's statements are non-actionable statements of opinion; and (5) Dr. Smith's statements are non-actionable forward-looking statements. *See* Co-Defendants' Mot. to Dismiss at 18-25 & Ex. 1 at 10-14. For example, Plaintiff seemingly takes issue with Dr. Smith's statements, when describing the RELIEF study, that "*this trial is a Phase II, quite well tested study design now*," (AC ¶ 167

(emphasis in original)) and “[t]he cutoffs that we used are very much based around trying to select patients who have sufficient cough and sufficient severity in order to be able to demonstrate differences in a clinical trial” (AC ¶ 168 (emphasis in original)); yet these are statements of opinion and are not false or misleading. Her other statements are similarly not actionable.

At bottom, and as explained in Co-Defendants’ motion to dismiss, Plaintiff’s lawsuit stems not from material misstatements or omissions but from his disagreement (fueled with the wisdom of hindsight) over the design of BELLUS’s clinical trial of the drug BLU-5937. Courts in this Circuit have held time and again that such disagreements are not actionable under the securities laws. *See Zagami v. Cellceutix Corp.*, No. 15-cv-7194 (KPF), 2016 WL 3199531, at *12 (S.D.N.Y. June 8, 2016).

2. Dr. Smith cannot face primary liability for statements made by others because the group pleading doctrine does not apply.

Recognizing that Dr. Smith’s statements are not actionable, Plaintiff also seeks to hold Dr. Smith responsible for alleged misstatements made by others. (AC ¶¶ 36-37.) She cannot be held primarily liable for any allegedly misleading statement that she did not make, however, because the group pleading doctrine upon which Plaintiff relies is not viable and does not apply to Dr. Smith. Under the group pleading doctrine, plaintiffs could “rely on a presumption that statements in prospectuses, registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company.” *In re BISYS Securities Litig.*, 397 F. Supp. 2d 430, 438 (S.D.N.Y. 2005) (citation and internal quotation marks omitted). The group pleading doctrine does not apply to Dr. Smith for two reasons.

First, the group pleading doctrine is no longer viable after the Supreme Court’s decision in *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). In *Janus*, the Supreme Court limited liability in a private securities fraud action under § 10(b) to parties that actually “make” misstatements of material fact, and the Supreme Court explained that the “maker” of the misstatement is “the person or entity with ultimate authority over the [mis]statement, including its content and whether and how to communicate it.” *Id.* at 142. As articulated in Judge Woods’s opinion in *In re Banco Bradesco S.A. Securities Litig.*, the group pleading doctrine is no longer viable after *Janus* “especially in light of the particularity requirements imposed on securities fraud pleadings by Rule 9(b) and the PSLRA.” 277 F. Supp. 3d 600, 637–41 (S.D.N.Y. 2017).³

Second, to the extent that the group pleading doctrine survives *Janus* as a general matter, it still would not allow this claim to survive against Dr. Smith, as she is a secondary actor to whom the group pleading doctrine does not apply. The group pleading doctrine is “‘extremely limited in scope,’ applying ‘only to clearly cognizable corporate insiders with active daily roles in the relevant companies or transactions.’” *Dresner v. Utility.com*, 371 F. Supp. 2d 476, 494 (S.D.N.Y. 2005) (quoting *Polar Int’l Brokerage Corp. v. Reeve*, 108 F. Supp. 2d 225, 237 (S.D.N.Y. 2000)). Secondary actors such as lawyers, “accountants, or other parties who are not employed by the issuing firm,” cannot be held liable for statements that are not attributed to them at the time of dissemination. *Pacific Inv. Management Co. LLC v. Mayer Brown LLP*, 603 F.3d 144, 148 & n.1 (2d Cir. 2010). Plaintiff does not allege that Dr. Smith is an employee of

³ But see *Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 805 (S.D.N.Y. 2018) (noting that “it is unclear whether the group pleading doctrine survives *Janus*.”); *Behrendsen v. Yangtze River*, No. 19-cv-24 (DLI), 2021 WL 2646353, at *10 (E.D.N.Y. June 28, 2021) (noting “a split among courts in the Second Circuit as to whether the group pleading doctrine remains viable after” *Janus*).

BELLUS – which she is not⁴ – let alone that she has an “active daily role[]” in the company’s business affairs. Instead, Plaintiff makes the conclusory allegation that Dr. Smith was “directly involved in the management and day-to-day operations of the Company’s primary focus, the clinical study of BLU-5937.” (AC ¶ 34.) Plaintiff’s failure to make particularized allegations as to Dr. Smith’s responsibilities for BELLUS’s public statements is fatal to his claim that Dr. Smith faces primary liability for statements that she did not make.⁵ *See In re Braskem S.A. Sec. Litig.*, 246 F. Supp. 3d 731, 762 & n.10 (S.D.N.Y. 2017).⁶

C. Plaintiff fails to plead loss causation.

Dr. Smith joins in the arguments made by Co-Defendants in Section I.C of their motion to dismiss the Amended Complaint to the extent applicable.⁷

II. Plaintiff fails to allege facts supporting statutory standing.

For the reasons set forth in Part III of Co-Defendants’ motion to dismiss the Amended Complaint, Plaintiff lacks standing to bring its claim against Dr. Smith under the Exchange Act.

⁴ Plaintiff alleges only that Dr. Smith is an advisor to BELLUS. (AC ¶ 32.).

⁵ Although Plaintiff does not include Dr. Smith in his claim under § 20(a) of the Exchange Act, he nevertheless alleges that she is a “control person” at BELLUS simply “[b]ecause of her position with the Company.” (AC ¶¶ 35, 36.) Such boilerplate allegations are also insufficient to establish liability for statements that Dr. Smith did not make. *See Youngers v. Virtus Investment Partners, Inc.*, 195 F. Supp. 3d 499, 524 (S.D.N.Y. 2016) (“[B]oilerplate allegations that a party controlled another based on officer or director status are insufficient.”) (citation omitted).

⁶ To the extent that this Court rejects Dr. Smith’s arguments regarding the import of *Janus* and her status as a secondary actor, Dr. Smith joins in the arguments made by Co-Defendants in Section I.B of their motion to dismiss the Amended Complaint, explaining that the other statements alleged in the Amended Complaint are not actionable.

⁷ Notably, the only alleged misstatements attributed to Dr. Smith in the Amended Complaint took place *after* the first alleged stock drop. (*See* AC ¶¶ 166–68, 172–73, 196–97.) For the reasons described in Co-Defendants’ motion to dismiss, Plaintiff fails to plead loss causation in relation to the second alleged stock drop. *See* Co-Defendants’ Mot. to Dismiss at 26.

III. Plaintiff fails to plead facts supporting personal jurisdiction.

The Amended Complaint must be dismissed because Plaintiff has not established personal jurisdiction over Dr. Smith. For the reasons set forth in Part V of Co-Defendant's motion to dismiss, Plaintiff fails to allege facts supporting specific personal jurisdiction. Plaintiff also fails to allege facts supporting general personal jurisdiction over Dr. Smith. The Amended Complaint does not allege that Dr. Smith, a professor in the United Kingdom, is "at home" in the United States. *See Daimler AG v. Bauman*, 571 U.S. 117, 138–39 (2014).

CONCLUSION

For all of these reasons, the Court should dismiss with prejudice Plaintiff's claim against Dr. Smith.

Dated: New York, New York
January 7, 2022

Respectfully submitted,

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